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QUALITY ASSESSMENT – LICENSED MEDICINE

RQA reference: L180227001

Product: Potassium Chloride 0.4mmol/mL Solution for Infusion
Two infusion bag presentations:
20mmol in 50ml
40mmol in 100ml

Supplier: Ennogen Healthcare Ltd.
Unit 4
Riverside Industrial Estate
Riverside Way
Dartford
DA1 5BS
UK

Licence Number: PL 40739/0044

Basis of Assessment: New product to market

Date of Report: 22 March 2018

Summary of Quality Assessment Outcome:

Medium Risk (product quality assessment based on High, Medium, Low risk for packaging and labelling) There is poor differentiation between products and labelling when containers are removed from the overwrap and container labels are difficult to read.

The use of Water for injection as an excipient is appropriate in that it produces an infusion of acceptable osmolarity (~800mOsmol/L) for central line administration.

Use of this licensed product should be considered to reduce risk to patients in clinical areas that currently use strong potassium chloride injection to prepare concentrated solutions for infusion. However to mitigate against risk of product miss-selection it is advised that clinical areas should only stock **either** minibags containing 20mmol in 50ml **or** 40mmol in 100ml according to most common clinical need.

	Observation
Final Container	Polyolefin/styrene infusion bags, sealed with aluminium, tamper evident port cover. Containers sealed in a clear overwrap.
Starting Materials	Potassium Chloride with excipients Water for Injections and Potassium Hydroxide for pH adjustment.
Labelling	Photographs: See Annex 1 The primary container labels are printed entirely in red directly on the clear infusion bag; there is poor differentiation between the two products. Title, strength and 'K' in larger and bold font with other text in smaller font size; In subdued light conditions and against various coloured backgrounds, labels are difficult to read and especially so when the outer wrap is in place. Container is printed with a bar code which can be electronically scanned through the clear overwrap. Batch number and expiry date are printed in black on the rear of the container.
Method of Manufacture	Manufactured, terminal sterilisation.
Product Release	Manufactured product for the market.
Latex status of - **Components**	No specific warnings.
Packaging	On the clear overwrap bag there is another label (see Annex 1), printed in bold, red text on a white ground. Title, strength, 'K' and the 'in use warning' are in an easily read font. There is poor differentiation between the two products.
Stability	20mmol in 50ml – 9 months from manufacture 40mmol in 100ml – 12 months from manufacture

Recommendations to purchaser:

- Be aware of product shelf life on delivery as it may be relatively short.
- To mitigate risk on product introduction, the attention of users to the poor differentiation between the 50ml and 100ml containers and the difficulties of reading the red printed label on the clear container, once the overwrap has been removed, must be highlighted.

Assessed by:

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Contributors:

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References:

MHRA Public Assessment Report, UKPAR, Potassium Chloride 0.4mmol/mL Solution for Infusion, UK Licence No: PL 40739/0044
Summary of Product Characteristics, Vers. Date of revision of text 04/09/17

Photographs